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No. 98-1768

IN THE
Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF FOR PRODUCT LIABILITY ADVISORY COUNCIL, INC., IN SUPPORT OF THE PETITION

Of Counsel:
HUGH F. YOUNG, JR.
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, Virginia 22091
(703) 264-5300

MALCOLM E. WHEELER *
WHEELER TRIGG & KENNEDY, P.C.
1801 California Street
Suite 3400
Denver, Colorado 80202
(303) 292-2525
Attorneys for Product Liability Advisory Council, Inc.

* *Counsel of Record*

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

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MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

Pursuant to Rule 37.2 of the Rules of this Court, the Product Liability Advisory Council, Inc. ("PLAC"), moves for leave to file the accompanying brief as *amicus curiae* in support of the petition for a writ of certiorari. Counsel for Petitioner has consented to the filing of the brief, but counsel for Respondent has withheld consent.

PLAC is an association of industrial companies that was formed for the principal purpose of submitting *amicus curiae* briefs in appellate cases involving significant issues affecting the law of product liability. Its members include manufacturers of a wide variety of products, including motor vehicles, pharmaceuticals, medical devices, pesticides, boats, aircraft, foodstuffs, and chemicals, who are governed by comprehensive federal safety regulations

and statutes, including statutes with preemption provisions. PLAC and its members therefore have a strong interest in the proper resolution of conflicts between the requirements of federal statutes and regulations, on the one hand, and state tort law, on the other.

Here, regulations promulgated by the Food and Drug Administration ("FDA") pursuant to the Medical Device Amendments of 1976 ("MDA")[1] specified the categories of information that a device manufacturer must provide to the FDA when applying for clearance to market a medical device. Those regulations did not state that the application must notify the FDA of the manufacturer's subjective intent regarding possible post-approval "off-label" uses[2] to which physicians might put the device. Instead, the regulations required the manufacturer to submit marketing materials that the manufacturer proposed to use to inform the medical community about the intended use of the device—specifically, "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use." 21 C.F.R. § 807.87 (1986).

Nevertheless, the court of appeals held that federal law neither expressly nor impliedly preempts a common-law fraud claim alleging that, in connection with an application for FDA clearance to market certain surgical screws,

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[1] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections at 21 U.S.C. §§ 360c *et seq.*).

[2] "Off-label" uses are uses of medical devices by physicians for purposes other than the intended uses specified in the devices' labeling approved by the FDA. Pet. App. 28a-29a (Cowen, J., dissenting). As Judge Cowen stated, "The FDA and the medical community have long recognized the importance of doctors' off-label uses of medical products. . . . Doctors may, in the exercise of their professional judgment, decide that based on current medical research an unapproved use of a product best serves a patient's needs." *Id.* at 29a.

Petitioner and its manufacturer client deceived the FDA by failing to tell it their subjective intent regarding post-clearance "off-label" uses. Under that holding, the individual states are free to maintain and enforce state standards that require manufacturers to provide to the FDA not only the information that the FDA itself considers necessary or useful in determining whether to permit a device to be marketed, but additional categories of information that state courts and juries decide should have been provided to the FDA under *their* interpretation of the MDA and FDA regulations. Moreover, that holding permits such state standards to be enforced in state fraud actions in addition to, and independent of, any claim seeking compensation based on allegations that the product was unreasonably dangerous or defective under state product-liability, negligence, or warranty laws.

In short, the decision below authorizes private rights of action that at bottom are based on alleged violations of federal laws requiring information disclosures to federal agencies, rather than on allegations that a product caused harm because it was unreasonably unsafe and defective.

The decision has substantial significance to PLAC, many of whose members are required by federal statutes and regulations to provide to federal regulatory agencies a variety of information about their products and businesses. If not reversed, that holding will have a profoundly deleterious effect not only on manufacturers of medical devices, but on all manufacturers in cases in which a federal preemption defense to such "fraud on the agency" claims is properly advanced. It will effectively require all manufacturers in all federally regulated industries to provide federal agencies not only with the information required by federal statutes and regulations as interpreted by the federal agencies themselves, but also with whatever in-

formation state courts and juries anywhere in the country might decide, under *their* interpretations, the federal agencies should have been provided and would have considered dispositive in deciding what action to take.

Accordingly, PLAC seeks to submit the accompanying brief to inform the Court of the importance of the issues raised by the petition, particularly as they affect manufacturers of products regulated by comprehensive federal safety regulations and statutes with preemption provisions, and the adverse consequences of leaving those issues unreviewed.

For the foregoing reasons, PLAC's motion for leave to file the accompanying brief as *amicus curiae* in support of the petition for a writ of certiorari should be granted.

Respectfully submitted,

Of Counsel:
HUGH F. YOUNG, JR.
PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, Virginia 22091
(703) 264-5300

MALCOLM E. WHEELER *
WHEELER TRIGG & KENNEDY,
P.C.
1801 California Street
Suite 3400
Denver, Colorado 80202
(303) 292-2525
Attorneys for Product Liability Advisory Council, Inc.

* *Counsel of Record*

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BRIEF FOR PRODUCT LIABILITY ADVISORY COUNCIL, INC., IN SUPPORT OF THE PETITION

INTEREST OF THE AMICUS CURIAE [1]

The interest of the *amicus curiae* is described in the accompanying motion for leave to file this brief.[2]

STATEMENT

Respondent represents thousands of plaintiffs who have sued Petitioner and others for damages and equitable relief

[1] Pursuant to Rule 37.6 of the Rules of this Court, *amicus curiae* states that no counsel for a party has authored this brief in whole or in part and that no person or entity other than *amicus curiae*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

[2] A list of the members of *Amicus Curiae* Product Liability Advisory Council, Inc., is in the attached Appendix.

for injuries allegedly suffered as a result of surgical implantation of certain screws for spinal fixation. The complaints contain multiple counts, one group of which charges Petitioner and medical device manufacturers with having defrauded the Food and Drug Administration ("FDA"). The decision below denominates these as " 'fraud on the FDA' claim[s]." Pet. App. 1a. Count I of the representative complaint addressed in the decision below is explicitly entitled "Fraud (on the FDA)." Pet. App. 8a.

The "fraud on the FDA" count does not allege that the screws were defective or unreasonably dangerous under product liability, negligence, or warranty principles. *See* Pet. App. 8a-9a. Rather, it alleges (a) that, in applying to the FDA in 1985 for clearance to market the devices, Petitioner "intentionally and falsely represented to the FDA" that the devices were "intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones"; (b) that, in fact, "the . . . device was intended exclusively for use in the spine"; (c) that the FDA "was ignorant of the fact that these devices and device components were intended by [the defendants] to be used as pedicle screw fixation devices"; (d) that the FDA would not have approved the device for marketing had it known Petitioner's actual subjective intent; and (e) that, as a result of that conduct, the plaintiffs represented by Respondent suffered physical harm. Pet. App. 8a-9a.

The application in question was made pursuant to what is commonly called a "section 510(k) notification," which is provided for in the Medical Device Amendments of 1976 ("MDA")[3] and codified at 21 U.S.C. §§ 360c(f)

[3] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections at 21 U.S.C. §§ 360c *et seq.*).

(1)(A)(i)-(ii) & 360e(b)(1)(B). Under that process the FDA can permit the marketing of medical devices, such as the devices in question, that are "substantially equivalent" to any of the devices marketed before the MDA's effective date and "grandfathered in" by the MDA under 21 U.S.C. §§ 360c(f)(1)(A)(i) & 360e(b)(1)(A).

FDA regulations in effect at the time of the alleged fraud specified the categories of information that a device manufacturer had to provide to the FDA in a section 510(k) notification. *See* 21 C.F.R. § 807.87 (1986). Those regulations did not state that the manufacturer had to notify the FDA of the manufacturer's subjective intent regarding possible post-clearance "off-label" uses to which physicians might put the device. Instead, the regulations required the manufacturer to submit written materials that the manufacturer proposed to use *overtly* to describe for the medical community the intended use of the device—specifically, "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use." *Id.*

Nevertheless, the court of appeals held that neither the MDA's express preemption provision, 21 U.S.C. § 360k, nor implied preemption principles preempted a "fraud on the agency" claim alleging that, in connection with the section 510(k) notification, the defendants had deceived the FDA by not telling the agency that they subjectively "intended [the devices] to be used" for spinal fixation, rather than "in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones." Pet. App. 8a-9a. The court of appeals thus held that a state may create and enforce a state common-law standard that makes medical-device manufacturers liable for omitting from their section 510(k) notifications information neither specifically required by FDA regula-

tions nor requested by the FDA. The court further held that causation could be based upon a jury's finding, without any prior ruling or opinion by the FDA, of what the FDA probably would have done had it received that information.

REASONS FOR GRANTING THE WRIT

UNLESS THIS COURT RESOLVES THE CONFLICT IN THE CIRCUITS OVER THE PREEMPTION OF "FRAUD ON THE AGENCY CLAIMS," THE CONFUSION IN THE LOWER COURTS WILL PREVENT THE CONSISTENT APPLICATION, AND UNDERMINE THE PURPOSES, OF A WIDE VARIETY OF FEDERAL STATUTES AND REGULATIONS

As the Petition shows in detail, the circuits are divided, and the lower courts generally are in a state of confusion, over whether various federal laws, including the MDA and its implementing regulations, preempt "fraud on the agency" claims brought under state laws. *See* Petition for Writ of Certiorari at 11-16, *comparing, e.g., Mitchell v. Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997) ("fraud on the FDA" claims preempted by MDA), *cert. denied*, 118 S. Ct. 1300 (1998), *Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997) ("fraud on the Coast Guard" claims preempted by Boat Safety Act), *cert. dismissed*, 118 S. Ct. 1793 (1998), and *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997) ("fraud on the Environmental Protection Agency" claims preempted by Federal Insecticide, Fungicide, and Rodenticide Act), *cert. denied*, 118 S. Ct. 1839 (1998), *with, e.g., Connelly v. Iolab Corp.*, 927 S.W.2d 848, 855 (Mo. 1996) ("fraud on the FDA" claims not preempted by MDA), *cert. dismissed*, 520 U.S. 1260 (1997), and *Hoelck v. ICI Americas, Inc.*, 584 N.W.2d 52, 61 (Neb. Ct. App.) ("fraud on the Environmental Protection Agency" claims not preempted by Federal Insecticide, Fungicide, and Rodenticide Act), *review denied* (Oct. 28, 1998). *See also Moore v. Brunswick Bowling & Billiards Corp.*, 889 S.W.2d 246 (Tex.) ("fraud on the Coast Guard" claims not preempted by Boat Safety Act), *cert. denied*, 513 U.S. 1057 (1994).

Without guidance from this Court, the purposes and policies of many federal statutes and regulations will be undermined in several important ways:

- Lower courts will apply preemption principles in an inconsistent manner.
- Federal statutes and regulations requiring manufacturers to disclose specified categories of information to federal agencies will be interpreted and applied by state courts and juries in an inconsistent and unpredictable manner.
- Manufacturers governed by those federal statutes and regulations will be confronted with the anomalous result of being left alone by the federal agency charged with promulgating and enforcing the disclosure requirements, yet subjected to liability, including liability for massive punitive damages, based upon varying interpretations and applications of those federal requirements by state courts and juries.
- Manufacturers will have little choice other than to inundate federal agencies with information and materials not actually required or wanted by the agencies, but that a state court or jury otherwise might conclude should have been provided to the agency.
- And manufacturers who state courts and juries decide should have disclosed different or additional information to federal agencies may be penalized by massive damages awards that result in increased consumer prices for, and reduced availability of, many beneficial products.

A. The Decision Below Undermines Congress' Intent Not to Create a Private Right of Action for Violations of FDA Regulations

Judge Cowen's dissenting opinion below described some of the harmful effects of the majority's decision in the FDA context as follows:

> It is hard to see why that is not in effect creating a private right of action for a violation of the FDA regulation, and it is difficult to reconcile that conclusion with a point the majority itself made in footnote 8: "controlling precedent bars recognition of a private cause of action under the FDCA, the MDA, or their implementing regulations." Given the demanding detail of the regulatory process, and the wide variety of violations ranging from the innocuous to the serious, recognizing a state cause of action for violations of FDA regulations will greatly distort the penalty scheme established by the statute. The penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion.

Pet. App. 28a (Cowen, J., dissenting). The majority did not disagree with that description of several ways in which judicial recognition of a state cause of action for violations of FDA regulations undermines federal purposes and policies. Nor did the majority disagree that the effect of recognizing a "fraud on the FDA" claim is to create a private right of action for a violation of the FDA section 510(k) notification regulation. Instead, the majority simply declared, "Nor do we hold, as suggested by the dissent, that any of the plaintiffs have stated a claim under the FDA's regulations," *id.* at 25a n.8, and "[i]t is, indeed, well established that Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA," *id.* at 13a.

But regardless of whether the "fraud on the FDA" claim was *formally* pled as "a claim under the FDA's regulations," the dissent was undeniably correct in observing that recognition of such claims *in effect* creates a private right of action for a violation of the FDA regulation. Specifically, the majority's decision permits each individual state to add a completely new private right of action to the pre-existing arsenal of (i) claims of defective design, manufacture, and warning under product-liability and negligence laws, (ii) claims alleging that fraudulent statements were made to physicians or patients, and (iii) claims based on express or implied warranties.

Thus, the decision permitting "fraud on the agency claims" does *not* merely preserve against preemption claims that would have existed in the absence of federal statutes and their implementing regulations. Like decisions by other lower courts holding "fraud on the agency" claims not preempted by other federal statutes and regulations, the decision below cannot be reconciled—other than on the most formalistic, blinkered basis—with its acknowledgment that "controlling precedent bars recognition of a private cause of action under the [federal statutes] or their implementing regulations." *Id.* at 25a n.8.

This is made even clearer by a fuller description of what the representative "fraud on the FDA claim" is *not*, and how it differs from other counts in the complaints:

- The "fraud on the FDA" claim is *not* that the device in issue was defective or unreasonably dangerous in its design, manufacture, or warnings under any state's product-liability or negligence law.
- It is *not* that the defendants made any false or misleading statement to any physician or patient. *See id.* at 26a (Cowen, J., dissenting).

- It is *not* that the device failed to meet the MDA's requirement of being "substantially equivalent to" the predicate devices on which Petitioner based the application. *Id.* at 25a-26a.
- It is *not* that the device was less safe than the predicate devices. *Cf. id.*
- It is *not* that the device was less fit for use for spinal fixation than were the predicate devices. *Cf. id.*
- And it is *not* that the "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use" submitted to the FDA pursuant to 21 C.F.R. § 807.87 differed from the labels, labeling, and advertisements that the defendants in fact intended to and did use after FDA approval. *Cf. id.*

Instead, the "fraud on the FDA" claim is solely that, in seeking clearance to market the device for "on-label" long-bone use, the defendants' subjective intent was to market it for "off-label" spinal use; that the FDA's regulations required disclosure of the subjective intent; that the defendants failed to disclose to the FDA that subjective intent; and that the plaintiffs were injured as a result of the nondisclosure. But if Congress had not created the FDA, and if the FDA had not promulgated its regulation requiring manufacturers to submit "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use," it would have been impossible for plaintiffs to have alleged that "fraud on the FDA" claim.

Accordingly, the majority below was incorrect in asserting that "it is clear that plaintiffs' 'fraud on the FDA' claims are based on state rather than federal law." Pet. App. 9a. Those claims could not have been made in the absence of, and therefore are based upon, the MDA and its implementing regulations.

B. Unless Resolved by This Court, the Conflict and Confusion in the Lower Courts Will Foster Uncertainty, Inefficiency, and Forum Shopping, and Will Undermine the Policies and Purposes of Many Federal Agencies

The range of adverse consequences generated by recognition of "fraud on the agency" claims is even greater than described by the dissent below. It is best appreciated by first observing that, to prevail on the representative claim addressed by the court below, plaintiffs must prove at least the following:

- The FDA required manufacturers not only to submit "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use," but to disclose to the FDA all "off-label" uses to which the manufacturer subjectively hoped physicians would put its devices.
- The manufacturer in fact defrauded the FDA by concealing its subjective intent.
- The FDA had no knowledge of the subjective intent from any other source.
- Had it known of the subjective intent, the FDA would not have cleared the device for marketing for the intended use objectively stated on the labels, labeling, and advertisements that were submitted pre-clearance and used post-clearance.

Plaintiffs' efforts to prove these elements in "fraud on the FDA claims," and other plaintiffs' efforts to prove similar elements in "fraud on the agency claims" based on other federal statutes and regulations, undermine federal purposes and policies in important ways. First, under the decision below, regulated companies must provide to federal agencies not only what the agencies themselves specifically say they want and consider material to safety determinations, but whatever the most extreme state court

or jury concludes should have been disclosed to the federal agency. This could include information that the agency did not intend to require and does not want.

The resulting state-imposed increase in the federal regulatory burden on the regulated companies, and the attendant state-imposed increased burden on federal agencies, would be contrary to federal policies and purposes. Indeed, even if the state laws as thus applied could fairly be said to promote a federal purpose of reducing the risk that defective products will be marketed, it still would conflict with the *method* chosen by Congress and the agency to reduce that risk. *Cf. International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) ("[I]t is not enough to say that the ultimate goal of both federal and state law is [the same]. A state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach this goal.").

In this case, for example, the FDA regulation in effect when the defendants submitted and obtained approval of their section 510(k) application did not specifically require disclosure of their subjective intent as to how the device might be used off-label by physicians. The representative complaint did not even allege that the FDA had ever stated that it intended or wanted its regulation to require statements of subjective purposes beyond those reflected in the manufacturers' written labeling and advertising. Nevertheless, the decision below permits plaintiffs to ask courts and juries in each state to interpret the regulation to require such disclosures.

The representative complaint also did not allege that the FDA had required manufacturers of the predicate devices to which the devices in issue were "substantially equivalent" to include labeling or advertising about "off-label" uses in spinal surgery. Thus, by subjecting manu-

facturers of new, but substantially equivalent, devices to the threat of massive fraud claims for failing to disclose a subjective intent that their devices be used exactly as the predicate devices were being used, the decision below interferes with section 510(k)'s purpose of fostering competition with "grandfathered" devices that were already on the market when the MDA took effect in 1976 and continued to be marketed thereafter. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996); App. 3a.

Second, as a result of the decision below, federal agencies will be burdened by plaintiffs' need, in a wide variety of "fraud on the agency" cases, to prove (i) that the federal agency intended its regulations to mean what the plaintiffs contend they mean, (ii) that the agency relied on the allegedly fraudulent statement, and (iii) that the agency would have taken some different action with respect to the device in question had it received the information the plaintiffs claim it should have received. Likewise, the agencies will be burdened by defendants' attempts in such cases to show (iv) that the agency did not intend to require the information that plaintiffs contend was fraudulently withheld, (v) that, whatever the agency's intent, the agency did not consider the information material to safety determinations, and (vi) that the agency would not have taken any different action had it received the information the plaintiffs claim it should have received. Those burdens will include, in numerous private lawsuits, requests under the Freedom of Information Act, 5 U.S.C. §§ 552, *et seq.*; petitions by plaintiffs asking the agencies to make findings that manufacturers failed to comply with the agencies' disclosure requirements, *see, e.g.*, Letter from Jeffrey L. Fazio to Enid Rubenstein, Office of Chief Counsel, National Highway Traffic Safety Administration, September 19, 1997; National Highway Traffic Safety Administration Special Order In Re PE85-05, PE87-

028, P85-24, September 23, 1997; and requests, by plaintiffs and defendants, for advisory opinions regarding agencies' interpretations of their regulations, *see, e.g., Montag v. Honda Motor Co.*, 75 F.3d 1414, 1418 (10th Cir.), *cert. denied*, 519 U.S. 814 (1996); 10 C.F.R. § 1.23(c) (1998) (providing for interpretive opinions by Office of the General Counsel, Nuclear Regulatory Commission); 21 C.F.R. § 10.85 (providing for advisory opinions by FDA Commissioner); 49 C.F.R. § 501.8 (d)(5) (1997) (providing for interpretive opinions by Chief Counsel, National Highway Traffic Safety Administration).

In particular, defendants will want to obtain from the agency as much information as possible showing that the agency's approval of the application would not have been affected by disclosure of the information that the plaintiffs claim should have been disclosed to it. In this case, for example, the defendants would want to obtain from the agency all agency documents showing at least the following:

- Agency officials understood, from their review of the defendants' first two section 510(k) notifications, which explicitly sought clearance to market the devices for use for spinal fixation, that the defendants hoped that physicians would use the devices "off-label" in that manner, even though the devices would be labeled and advertised solely for long-bone use.
- The predicate devices on which the section 510(k) notification was based had been used "off-label" for spinal fixation, and agency officials knew it.

These many and varied types of information requests by private plaintiffs and defendants impose on the agency the burden of either responding to the requests or refusing

to produce the information and then defending against litigated efforts to compel production.

Third, to the extent that a federal agency succeeds in protecting such information from disclosure—for example, by invoking limits or exemptions under the Freedom of Information Act—litigants in "fraud on the agency" litigation will be prevented from presenting to courts and juries crucial evidence of what the agency intended its regulation to mean, what information the agency considered material, whether the agency relied on the defendants' allegedly false statements, whether the agency knew about the allegedly withheld information from any other source, and whether the agency would have taken any different action absent the alleged fraud. Courts and juries thus will largely have to speculate about the most central elements of "fraud on the agency" claims.

In speculating what action the agency would have taken and why it would have taken it had the agency been provided with the information, the state court or jury may miss the mark completely and reach a conclusion flatly contrary to the one the agency would have reached in furtherance of federal purposes and policies. Here, for example, although plaintiffs filed with the FDA comments alleging the same fraud alleged in the representative complaint addressed in the decision below, the FDA later "granted permission for the bone screws at issue to be labeled for use in spinal fixation." Petition at 17 n.7, citing *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1995 WL 764580, at *5-*6 (E.D. Pa. Dec. 14, 1995); 63 Fed. Reg. 40025 (1998).

These dangers to federal purposes and policies are substantial, and the uncertainties legion. Here, for example, the decision below emphasizes that the representative complaint alleges that the defendants subjectively in-

tended the device in question to be "*exclusively* for use in the spine" when they filed their section 510(k) notification. App. at 8a (emphasis added). But could a "fraud on the agency" claim likewise proceed if the defendants secretly hoped that 90%, rather than 100%, of post-clearance sales would be for "off-label" use in spinal surgery? 50%? 10%? Would it make any difference if the defendants hoped that the "off-label" use would be minimal at first, but build over a period of several years? Would it make any difference if, when the defendants filed their section 510(k) notification, they hoped that "off-label" uses would occur post-clearance, but they changed their minds before clearance was granted? If they changed their minds the day after clearance was granted? Would federal policies and purposes be rationally served by allowing "fraud on the agency" claims if the subjective intent was formed one week before clearance was granted, but not if the subjective intent was formed one week after clearance was granted, especially where the claim is *not* that the device was defective or unreasonably dangerous?

As for the subjective intent itself, which of the manufacturer's officers, directors, and employees' subjective intent must be disclosed under this state-law interpretation of the federal regulation? For example, which corporate employee's subjective hope that the devices will be used "off-label" for spinal fixation is the subjective intent that matters for "fraud on the agency" claims, especially when the objective labeling and advertising used by the manufacturer properly identify long-bone use as the intended use? What if the chief financial officer harbors that subjective intent, but the chief executive officer does not? What if neither of them harbors that intent, but the marketing director does?

All of these are questions that the federal agency charged by Congress with promulgating and enforcing the regulations should answer. The agency knows what information it needs and wants, and for what purposes. The agency knows what information is important enough to warrant enforcement proceedings when that information is withheld or misrepresented. The agency knows what balance it wishes to strike between ensuring informed decision-making and imposing such massive penalties that competition is impaired, the public is deprived of certain products, the prices of medical devices unduly increase, or the regulated entities inundate the agency with unwanted information in order to avoid such penalties in the future.

Here, in particular, Congress recognized as much by enacting as part of the MDA a broad preemption provision that prohibits the states from establishing

> any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k. The "fraud on the FDA" claim runs afoul of that express preemption provision, and it also violates conflict-preemption principles in two separate respects.

First, because the FDA's regulations required the section 510(k) notification to include only "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use," not a statement of the manufacturer's subjective intent regarding hopes for post-clearance "off-label" uses, the "fraud on the FDA" claim requires information that is

both "different from" and "in addition to" the federal requirements. Second, state laws requiring payment of damages under a "fraud on the agency" claim that does not compensate plaintiffs for harm caused by a product defect impose a requirement that is "different from" and "in addition to" any enforcement requirement that the FDA might choose to impose. At a minimum, the state actions thus conflict with the *method* chosen by Congress and the agency to balance the need for enforcement of federal information-disclosure requirements and the federal goals of fostering competition with "grandfathered" devices, ensuring the availability of important medical devices, and reducing the prices of those devices.

Also, Congress gave the FDA discretion to decide whether a violation of an FDA regulation is a type that should be penalized in any fashion or, instead, whether the public would be disserved by imposing any penalty at all. *See* 21 U.S.C. §§ 336, 337(a). Therefore, it would undermine federal purposes and policies if, as here, the agency determined that no penalty should be imposed for a particular failure to disclose, but private plaintiffs in every state could bring multiple lawsuits based solely on the same nondisclosure and recover millions of dollars in compensatory and punitive damages.

Nor can it be argued that Congress intended to permit the individual states to undermine federal policies and purposes in these numerous ways in order to enable states to compel manufacturers to compensate consumers injured by defective and unreasonably dangerous products. Preemption of "fraud on the agency" claims in no way precludes *any* claim alleging strict product liability, negligence, or breach of warranty for *any* injury caused by *any* allegedly defective or unreasonably dangerous product. Certainly, unlike the manufacturer in *Medtronic*, Petitioner here did not argue that "Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device." *Medtronic*, 518 U.S. at 487.

Accordingly, unlike the preemption of defect-based claims in *Medtronic*, preemption of "fraud on the agency" claims would not have "the perverse effect of granting complete immunity from design defect liability to an entire industry." *Id.* Instead, a failure to hold such claims either expressly or impliedly preempted would have the perverse effect of subjecting manufacturers to massive liability under claims alleging no defect at all. If a device is not defective, so that the plaintiff would recover nothing absent the separate "fraud on the agency" claim, any physical harm the plaintiff may have incurred is causally related to the alleged fraud only in a formal "but for" sense, in the same manner that a pedestrian's injury when struck by a non-negligent driver with an expired license is caused by the violation of the law requiring a valid license.

"Fraud on the agency" claims differ dramatically from product-defect claims in another major respect. When considering whether Congress intended to preempt state laws authorizing damages awards based on alleged product defects, it sometimes can be said that Congress intended the agency's product design or performance requirements to set a "floor," not a "ceiling," on what constitutes an unreasonably unsafe product. Where applicable, that anti-preemption argument can make sense because Congress reasonably could have decided to allow the individual states to decide the levels of product risks to which they are willing to have their citizens exposed. That rationale could not, however, justify a decision not to preempt "fraud on the agency" claims that are over and above any defect claim. "Fraud on the agency" claims go

only to what information the federal agency itself wants to consider and for what purposes, and the states have no basis for substituting their own judgments for those of the agency by forcing manufacturers to provide the agency with additional information or to penalize manufacturers when nondisclosures occur.

This Court repeatedly has emphasized that "[t]he purpose of Congress is the ultimate touchstone" in determining whether preemption precludes the states from using state law to prosecute alleged violations of federal statutes and regulations. *Medtronic*, 518 U.S. at 485. Here, as in several other federal statutes, Congress enacted a broad preemption provision. It should not be read in a way that assigns to Congress an intent to do the absurd. It is all but inconceivable that Congress would have intended to allow individual states to enact statutes requiring manufacturers to disclose to federal agencies specific information that the agencies had not specified in their own disclosure requirements. It is almost as implausible that Congress would have intended to allow individual states to enact statutes imposing multi-million-dollar civil penalties on manufacturers for failing to disclose to the federal agencies specific information that the agencies had specified in their own disclosure requirements. Any such scheme would give to every state the power to override the agency's determination as to whether the failure was significant enough, or sufficiently related to the determination of product safety, to make any penalty at all desirable and, if so, the appropriate size of the penalty. In addition, since "fraud on the agency" claims do not rest on proof of a defective or unreasonably dangerous design, everyone injured in connection with a reasonably safe product could sue, collectively drive the defendant into bankruptcy, impair the competition that the federal law—here, the section 510(k) process—was

intended to foster, and increase the prices of beneficial products needed or desired by consumers.

The fact that the states may choose to impose these penalties through common-law standards, rather than through statutory standards, makes the undermining of federal purposes and policies no less substantial. *See, e.g., Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992) (rejecting argument that Federal Aviation Act preempts "only state laws specifically addressed to the airline industry" and not "laws of general applicability" because that interpretation would create an "utterly irrational loophole"). The state standards still conflict with federal law, and they still are preempted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Of Counsel:
HUGH F. YOUNG, JR.
PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, Virginia 22091
(703) 264-5300

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MALCOLM E. WHEELER *
WHEELER TRIGG & KENNEDY, P.C.
1801 California Street
Suite 3400
Denver, Colorado 80202
(303) 292-2525
Attorneys for Product Liability Advisory Council, Inc.

* *Counsel of Record*

APPENDIX

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PRODUCT LIABILITY ADVISORY COUNCIL, INC.
CORPORATE MEMBERS

3M
Allegiance Healthcare Corporation
Aluminum Company of America
American Home Products Corporation
American Medical Systems, Inc.
American Suzuki Motor Corporation
Andersen Corporation
Anheuser-Busch Companies, Inc.
Appleton Papers, Inc.
Atlantic Richfield Company
BASF Corporation
Baxter International, Inc.
Bayer Corporation
Becton-Dickinson & Company
BIC Corporation
Black & Decker (U.S.) Inc.
BMW of North America, Inc.
Boeing Company, The
Bombardier Inc., Recreational Products
Bridgestone/Firestone, Inc.
Briggs & Stratton
Brown-Forman Corporation
Budd Company, The
C. R. Bard, Inc.
Caterpillar, Inc.
Celanese Ltd.
CLARK Material Handling Company
Coleman Company, Inc., The
Continental General Tire, Inc.
Coors Brewing Company
Corning Incorporated
DaimlerChrysler Corporation
Dana Corporation
Deere & Company
Digital Equipment Corporation
Dow Chemical Company, The
E. & J. Gallo Winery
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Estee Lauder Companies
Exxon Corporation, U.S.A.
FMC Corporation
Ford Motor Company
Fortune Brands, Inc.
Freightliner Corporation
Gates Corporation, The; Stant Corporation
General Electric Company
General Motors Corporation
Georgia-Pacific Corporation
Glaxo Wellcome Inc.
Goodyear Tire & Rubber Company, The
Great Dane Limited Partnership
Guidant Corporation
Harley-Davidson Motor Company
Harnischfeger Industries Inc.
Heil Company, The
Hoechst Marion Roussel, Inc.
Honda North America, Inc.
Hyundai Motor America
International Paper Company
Isuzu Motors America, Inc.
Johnson & Johnson
Johnson Controls, Inc.
Joseph E. Seagram & Sons, Inc.
Kawasaki Motors Corp., U.S.A.
Kolcraft Enterprises, Inc.
Kraft Foods, Inc.
Loewen Group International, Inc.
Lucas Variety

Lucent Technologies Inc.
Mack Trucks, Inc.
Mazda (North America), Inc.
Medtronic, Inc.
Melroe Company
Mercedes-Benz of North America, Inc.
Michelin North America, Inc.
Miller Brewing Company
Mitsubishi Motors R. & D. of America, Inc.
Motor Coach Industries International, Inc.
Navistar International Transportation Corp.
Nissan North America, Inc.
O. F. Mossberg & Sons, Inc.
Otis Elevator Co.
PACCAR Inc
Panasonic Company
Pentair, Inc.
Pfizer Inc
Philip Morris Companies, Inc.
Porsche Cars North America, Inc.
Procter & Gamble Co., The
Raymond Corporation, The
Raytheon Aircraft Company
Rheem Manufacturing
RJ Reynolds Tobacco Company
Rover Group, Ltd.
Schindler Elevator Corp.
SCM Group USA, Inc.
Sears, Roebuck and Company
Shell Oil Company
Siemens Corporation
Smith & Nephew, Inc.
SmithKline Beecham Corporation
Snap-on Incorporated
Sofamor Danek Group, Inc.
Solutia Inc.
Sturm, Ruger & Co., Inc.
Subaru of America
Taylor Wharton Gas Equipment, A Division of Harsco
Tenneco Automotive
Terex Corporation
Textron Inc.
Thomas Built Buses, Inc.
Toro Company, The
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Inc.
UST (U.S. Tobacco)
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.